MAY - 2 2000

10.510(K) SUMMARY

K000480

Company Name and Address

Electroscope, Inc.
4828 Sterling Drive
Boulder, CO 80301-2350

Phone: 303-444-2600
Fax: 303-444-2693

Company Contact Person

Judith King
Manager, Regulatory Affairs and Quality Assurance

Phone: 303-444-2600, ext. 117
Fax: 303-444-2693

Manufacturing Facility Name and Address

Electroscope, Inc.
4828 Sterling Drive
Boulder, CO 80301-2350

Reason for 510(k)

Device modification

Common, Classification & Proprietary Names

Common Name:	electrosurgical electrode accessory monitor
Classification Name:	electrosurgical cutting and coagulation device and accessories
Proprietary Name:	Active Electrode Monitoring System

Classification

Class:	II
Panel:	General and Plastic Surgery
CFR Section:	21 CFR 878.4400
Product Code:	79GEI

Name(s) of the Device

Active Electrode Monitoring System

Intended Use

The Electroscope Active Electrode Monitoring System is an accessory for use with electrosurgical generators and electrodes that is designed to safely deliver electrosurgical energy and to prevent injury caused by insulation failure and capacitive coupling.

The Active Electrode Monitoring System consists of two distinct functions:

- *Active Electrode Monitoring* is intended to control stray monopolar energy caused by insulation failure and capacitive coupling in surgical instruments on the shaft of the instrument.

- *End Point Monitoring* is intended to aid the surgeon in determining the endpoint of bipolar electrosurgical desiccation.

Description of the Device Modifications

The subject of this submission is a modified version of the Electroshield Monitoring System for use with single pad patient return electrodes and electrosurgical units that are not equipped with or do not require the use of contact quality monitoring. The Active Electrode Monitoring (AEM) System is a modification of the existing Electroshield Monitoring products as follows:

- The return electrode connector receptacle has been modified to be compatible with the pin connector configuration of single pad patient return electrodes.
- The product labeling (operator's manual) has been modified to specify the use and provide appropriate instructions, warning, and cautions for use of the device with single pad patient return electrodes and non-CQM electrosurgical generators.

Identifcation of Predicate Devices

Electroshield Monitoring System	ElectroScope, Inc.	K913625
Force FX ElectroSurgical Generator	Valleylab, Inc.	K944602

This is based upon substantial equivalence in intended use, design and performance.

Conclusion

Based on the information provided in this premarket notification, it is concluded that the Active Electrode Monitoring System is substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2000

Electroscope, Inc.
c/o Ms. Lynne Aronson
Senior Consultant
Morningstar Consulting Group, Inc.
P.O. Box 219
Indian Hills, Colorado 80454

Re: K000480
Trade Name: Active Electrode Monitoring (AEM) System
Regulatory Class: II
Product Code: GEI
Dated: February 10, 2000
Received: February 14, 2000

Dear Ms. Aronson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
And Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. INDICATIONS FOR USE FORM

K000480

Device Name:

Active Electrode Monitoring (AEM) System

Indications for Use:

The Electroscope Active Electrode Monitoring System is designed to safely deliver electrosurgical energy and to prevent injury caused by insulation failure and capacitive coupling.

The Active Electrode Monitoring System consists of two distinct functions:

Active Electrode Monitoring is intended to control stray monopolar energy caused by insulation failure and capacitive coupling in surgical instruments on the shaft of the instrument.

End Point Monitoring is intended to aid the surgeon in determining the endpoint of bipolar electrosurgical desiccation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lachman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000480

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)